

NEO New Oncology GmbH • Gottfried-Hagen-Str. 20 • 51105 Köln

Firma

Kontaktperson

Straße

PLZ, Ort

27.09.2019

## NEOonsite may provide inaccurate mutation results

Dear customer,

according to our documents, you are using the following product(s):

- **NEOonsite**

### **Reason for the correction and when does this issue occur?**

The detected di-, tri-, or oligonucleotide mutations (DNMs, TNMs, ONMs) by the bioinformatic pipeline consist of adjacent point mutations that must pass the NEO-internal filter criteria. Depending on the fulfillment of the criteria, the individual mutation position is annotated as 'PASS' or 'NON-PASS'. For DNMs, TNMs or ONMs, the pipeline internally annotates two, three or more "PASS" or "NON-PASS" annotations for one event. If a DNM, TNM, or ONM contains at least one 'PASS' point mutation, this value would need to be converted to a single 'PASS'. However, the pipeline always incorrectly converts the complex filter annotation of DNMs, TNMs, and ONMs to 'NON-PASS', meaning that DNMs, TNMs, and ONMs always have the 'NON-PASS' filter in NEOdiagnosis.

This issue is limited to test results from the 26th of July 2019 on. NEO checked all customer samples which were processed since the 26th of July 2019 and already notified the affected customers.

### **What are the possible risks to health?**

The current bug in the pipeline and thereby the presentation in NEOdiagnosis is not limited to specific genes. Some of adjacent point mutations, which have been falsely reported as 'NON-PASS', could be clinically relevant due to the presence of approved targeted therapies.

### **What steps is taken by us to avoid the possible risks associated with this issue?**

- NEO will check all customer samples to ensure that falsely annotated mutations are not missed by informing the customer the day the results are uploaded on NEOdiagnosis. If test results from your site are found to be discrepant, you will be notified.

### **What steps can the user take to avoid the possible risks associated with this issue?**

- In the module NEOdiagnosis, in the mutation tab, filter for the 'Annotation column' to ensure that clinically relevant alterations are not missed.

### **How will the issue finally be resolved?**

NEO New Oncology GmbH will patch the system to correct the filtering of di-, tri-, or oligonucleotide mutations as quickly as possible. We strive for the highest level of safety and quality.

### **Dissemination of the content of this notice**

Please ensure that all users of the affected products within your organization, and others, who may need to be informed receive the safety relevant information provided with this notice and will comply with the recommendations therein.

We appreciate your understanding and cooperation with this safety advisory and ask you to immediately instruct your personnel accordingly. Please ensure that this safety advisory is retained in your product related records appropriately. Please keep this information at least until the measures have been finalized.

### **Acknowledge Receipt of this Safety Advisory Notice**

Please fill out the attached Acknowledgment of receipt and follow the instructions for sending it back to NEO New Oncology GmbH via fax (+49 (0) 221 / 888238-22), e-mail ([info@newoncology.de](mailto:info@newoncology.de)) or hand it to one of our NEO New Oncology field team members.

The Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) is informed about this notice.

Sincerely Yours,

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Safety Officer

## **Acknowledgement of receipt**

**FAX-reply to: +49- (0)221-888 238-22**

or

**Email to: [qm@newoncology.de](mailto:qm@newoncology.de)**

### **NEOonsite may provide inaccurate mutation results**

Customer address:

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I hereby confirm as the owner / responsible operator of NEOonsite that I have read and understood this notice and accept the implementation of the recommended measures.

Place, Date: \_\_\_\_\_

Name: \_\_\_\_\_

Signature: \_\_\_\_\_